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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,881	01/11/1999	THAI D. NGUYEN	07425.0057	7578

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EXAMINER	
SCHMIDT, MARY M	

ART UNIT	PAPER NUMBER
1635	18

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/227,881	Applicant(s) NGUYEN ET AL.	
	Examiner Mary Schmidt	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *79-81 and 91-126* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *79-81,91,96,97,100,102,103,106,108,109,112,114,121,124 and 126* is/are rejected.

7)☒ Claim(s) *94,115,118 and 120* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continuation of Disposition of Claims: Claims withdrawn from consideration are 92,93,95,97-99,101,104,105,107,110,111,113,116,117,119,122,123 and 125.

DETAILED ACTION

1. Please note that the Examiner of record has changed in the instant Application. Please address future correspondence to Examiner Schmidt (for information on how to reach examiner, please see the concluding remarks below).

2. The pending claims are claims 79-81 and 91-126.

3. Claims 92, 93, 95, 98, 99, 101, 104, 105, 107, 110, 111, 113, 116, 117, 119, 122, 123, and 125 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected SEQ ID NOS., there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No 23. Applicant is reminded that upon issuance of a final rejection in subsequent Office Actions, Applicant will be required to amend claims 79, 81, 91, 97109, 115, 121 and 103 to claim only compositions pertaining to the elected SEQ ID NO:3.

4. Claims 94, 115, 118 and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Applicant is advised that should 115 be found allowable, claim 118 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof since the breath of claimed SEQ ID NO:3 would be identical. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper

after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 79, 80, 81, 91, 96, 97, 100, 102, 103, 106, 108, 109, 112, 114, 115, 121, 124 and 126 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to fragments and sequences comprising fragments of or the sequences of comprising SEQ ID NO:3 or fragments thereof, vectors and cells expressing said constructs, which are not considered adequately described by the specification as filed.

The specification as filed teaches that SEQ ID NO:3 is a 5' regulatory region of a human TIGR gene, where TIGR stands for trabecular meshwork inducible glucocorticoid response protein gene. The specification as filed does not describe the specific regions by way of sequence structure which correlate to the functional regions for initiation of TIGR gene expression. Nor does the specification as filed teach sequences comprising SEQ ID NO:3 for

instance containing the gene coding region for the TIGR gene. The sequences of SEQ ID NO:1, 2 and 34 in the specification do not remedy this lack of specific guidance since they too are portions of the 5' regulatory region of the TIGR gene.

MPEP 2163 teaches the following conditions for the analysis of the claimed invention at the time the invention was made in view of the teachings of the specification and level of skill in the art at the time the invention was made:

> **The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence....A lack of written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process....Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement....The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.**

In the instant case, the invention as a whole, any nucleic acid sequence fragment of SEQ ID NO:3 or any larger sequence comprising SEQ ID NO:3, is not adequately described in view of the lack of disclosure of the specific identifying characteristics, ie. sequence structure, of any such fragments or larger sequences having a specified correlation to the function of SEQ ID

NO:3 as the regulatory region for the TIGR gene. One of skill in the art at the time the invention was made would not have been able to immediately envisage the sequence of any mutation, addition or deletion of the sequence of SEQ ID NO:3 having the same functional properties. As such, one of skill in the art would not have recognized that Applicant was in possession of a representative number of species of the breath of claimed fragments and sequences comprising SEQ ID NO:3 at the time the invention was made.

Furthermore, claims 109, 103, 106, 108, 112, 114, and 80 are not adequately described for any "cell" but only an "isolated cell" in view of the unpredictability in the art for gene making recombinant cells *in vivo*. Applicant has not provided any guidance in the specification as filed to support a written description of the claimed SEQ ID NO:3 in cells in a whole organism. Note Anderson teaches on page 25, col. 2, that [t]he problems that investigators face in developing retroviral vectors that are effective in treating disease are of four main types: obtaining efficient delivery, transducing non-dividing cells, sustaining long-term gene expression, and developing a cost-effective way to manufacture the vector." They further teach on page 30, col. 1, that "[t]he reason for the low efficiency of gene transfer and expression in human patients is that we still lack a basic understanding of how vectors should be constructed, what regulatory sequences are appropriate fro which cell types, how in vivo immune defenses can be overcome.... It is not surprising that we have not yet had notable clinical successes. Verma et al. further taught (page 239) that "[i]n principle, gene therapy is simple: putting corrective genetic material into cells alleviates that symptoms of disease. In practice, considerable obstacles have emerged....

Although many somatic tissues can receive therapeutic DNA, the choice of cell usually depends on the nature of the disease. Sometimes a clear definition of the target cell is needed." The specification as filed does not provide a representative number of cells having the SEQ ID NO:3 expressed *in vivo* to show that Applicant was in possession of a representative number of species of any such cell. Since level of skill to genetically engineer cells *in vivo* is extremely high, the specification as filed would have necessarily provided substantial written description guidance in the area of gene therapy to envision non-isolated cells, ie. cells *in vivo*, having the claimed substantially purified nucleic acid of SEQ ID NO:3, a functional regulatory region.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

SEAN McGARRY
PRIMARY EXAMINER
1635

M. M. Schmidt
September 9, 2002